

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: COLOMBO ET AL-3 PCT  
PCT NO.: PCT/EP2004/050371 PCT FILED: MARCH 26, 2004  
SERIAL NO: 10/593,861 FILED: SEPTEMBER 22, 2006  
TITLE: INSULIN HIGHLY RESPIRABLE MICROPARTICLES

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

**MAIL STOP PCT**

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

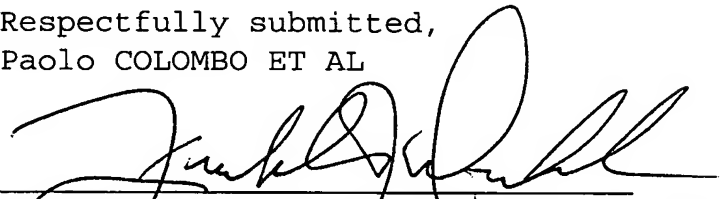
Dear Sir:

Supplemental to the Information Disclosure Statement dated December 28, 2006, Applicants are enclosing Form PTO-1449 and copies of the articles cited thereon. These documents were cited in the specification as well as on the original PTO Form 1449 filed December 28, 2006. The last article, reference "AV" is a new reference for the Examiner's consideration.

It is respectfully requested that the foregoing Supplemental Information Disclosure Statement (IDS) be incorporated into the official file of the present patent application.

Because this Supplemental IDS is being filed before a first Office Action on the merits, it is believed that no fee is required. However, if a fee should be required for this IDS, the Commissioner of Patents and Trademarks is hereby authorized to charge any required fee, or to credit any overpayment to Deposit Account No. 03-2468.

Respectfully submitted,  
Paolo COLOMBO ET AL



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Enclosures: PTO-1449 form with eleven (11) articles

cmm

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450 on January 16, 2007.



Kelly Espitia

FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. : <b>COLOMBO ET AL-3 PCT</b>	SERIAL NO. <b>10/593,861</b>
LIST OF REFERENCES CITED BY APPLICANT  (Use several sheets if necessary)		APPLICANT : <b>Paolo COLOMBO ET AL</b>	
		FILING DATE: <b>September 22, 2006</b>	GROUP:

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,338,931	07/1982	Cavazza Claudio			
	AG						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AH							
	AI							

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AL		A.L. Jones et al., "An Investigation of the Pulmonary Absorption of Insulin in the Rat." "Proceedings of the third European..." 1987, vol. 2, pgs. 143-149. (Spec)
	AM		Colthorpe et al., "The Pharmacokinetics of Pulmonary-Delivered Insulin: A Comparison of Intratracheal and Aerosol Administration to the Rabbit." Pharmaceutical Research, 1992, vol. 9, pgs. 764-768. (Spec)
	AN		Komoda, F. et al., "Intratracheal Delivery of Peptide and Protein Agents: Absorption from Solution and Dry Powder by Rat Lung." J. Phar. Sci., 1994, vol. 83, pgs. 863-867. (Spec)
	AO		"Monomeric Insulins and Their Experimental and Clinical Implications." Diabetes Care, 1990, vol. 13, pgs 953-954. (Spec)
	AP		Lee, S. et al., "Development of an Aerosol Dosage Form Containing Insulin." J. Phar. Sci., 1976, vol. 65, pgs. 567-572. (Spec)
	AQ		Patton, J.S. et al., "Inhaled Insulin", Advanced Drug Delivery Reviews 35, 1999, pgs. 235-247. (Spec)
	AR		Edwards, D.A. et al., "Recent advances in pulmonary drug delivery using large, porous inhaled particles." J. App. Physiol., 1998, vol. 85, pgs. 379-385. (Spec)
	AS		Nagai, T. et al., "Powder dosage form of insulin for nasal administration." J. Contr. Rel., 1984, vol. 1, pgs. 15-22. (Spec)
	AT		Rydén, L. et al., "Effect of polymers and microspheres on the nasal absorption of insulin in rats." Int. J. Pharm. 1992, vol. 83, pgs. 1-10. (Spec)
	AU		European Pharamcopeia, 4 <sup>th</sup> Edition, "Preparations for inhalations: Procedure for powder inhalers." <2.9.18> pg. 216-217. (Spec)
	AV		European Pharamcopeia, 4 <sup>th</sup> Edition, "Insulin, Bovine; Insulin, Human..." pgs 1368-1381.

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.